

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 19, 2020

Abigail Wacek Senior Regulatory Consultant Sciessent LLC 100 Cummings Center Suite 251-G Beverly, MA 01915

Subject: Label and CSF Amendment – Updating the Active Ingredient Statement as

required by the GDCI Notice

Product Name: Agion® Silver Antimicrobial Type AD

EPA Registration Number: 88165-1 Application Date: 01/03/2020 Decision Number: 559688

Dear Ms Wacek:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF:

Basic CSF dated 01/03/2020

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process.

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Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at Heffernan.Aline@epa.gov.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Steven Dryderman

Enclosure: Stamped Label

## Agion® Silver Antimicrobial Type AD

A preservative and bacteriostatic agent for use in the manufacture of polymer, plastic and latex products. For commercial and industrial use.

### **Active Ingredient:**

Silver ion 22.00 % Other Ingredients 78.00 % Total 100.00 %

ACCEPTED

02/19/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 88165-1

## **KEEP OUT OF REACH OF CHILDREN CAUTION**

#### SEE INSERT LABEL FOR PRECAUTIONARY STATEMENTS

Manufactured for: Sciessent LLC 100 Cummings Center Suite 251-G Beverly, MA 01915

EPA Registration No. 88165-1 EPA Establishment No. 71227-JPN-001

**Net Wt. XXXX** 

Lot No. XXXXXXXXX

## **Directions for Use**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Agion Silver Antimicrobial Type AD is an antimicrobial additive to be used by compounding into many polymeric materials. It is designed to be incorporated during the manufacturing process to impart antimicrobial activity to the manufactured products. Agion Silver Antimicrobial Type AD suppresses the growth of algae, mold, mildew, fungi and bacteria which cause unpleasant odors, discoloration, staining, deterioration or corrosion only. No finished product incorporating Agion Silver Antimicrobial Type AD may make any public health claims relating to antimicrobial activity without first obtaining an EPA registration or FDA clearance for the finished product which permits such claims, and without a tolerance or exemption from the requirement of a tolerance. When incorporated into treated articles, this product does not protect users of any such treated article or others against food borne or disease causing bacteria, viruses, germs or other disease causing organisms.

#### **Types of Finished Products**

#### Plastics - including films, sheets, slabs, and molded plastic parts

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.1% for bulk plastics. Contact Sciessent LLC to determine the appropriate amount of *Agion Silver Antimicrobial Type AD* for individual finished products.

#### Non-food contact uses only:

Medical Devices, Equipment and Supplies

#### **Fibers**

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.1% for fibers. Contact Sciessent LLC to determine the appropriate amount of *Agion Silver Antimicrobial Type AD* for individual finished products.

#### Non-food contact uses only:

Medical Devices, Equipment and Supplies

#### **Coatings, Films and Laminates**

The additive may be incorporated into the coating, film or laminate applied to the finished product at up to 5.0% by weight, or at least 0.05% for paper or 0.1% for bulk plastics. Contact Sciessent LLC to determine the appropriate amount of *Agion Silver Antimicrobial Type AD* for individual finished products. Types of coatings include water-borne, solvent-borne, 100% solids, radiation cure, liquid and powder.

#### Non-food contact uses only:

Medical Devices, Equipment and Supplies

#### **Adhesives and Sealants**

The additive may be incorporated into the finished product at up to 5.0% by weight, or at least 0.05% for paper or 0.1% for bulk plastics. Contact Sciessent LLC to determine the appropriate amount of *Agion Silver Antimicrobial Type AD* for individual finished products.

#### Non-food contact uses only:

Medical Devices, Equipment and Supplies

#### **Miscellaneous Applications**

The additive may be incorporated into the finished product at up to 5.0% by weight or at least 0.1%. Contact Sciessent LLC to determine the appropriate amount *of Agion Silver Antimicrobial Type AD* for individual finished products.

#### Non-food contact uses only:

**Indoor Paints and Coatings** 

#### PRECAUTIONARY STATEMENTS

**Hazards to Humans and Domestic Animals:** Harmful if absorbed through skin, inhaled, or swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
If on skin	Take off contaminated clothing.
	Rinse skin immediately with plenty of water for 15 – 20 minutes.
	Call a poison control center or doctor for treatment advice.
If inhaled	Move person to fresh air.
	• If person if not breathing, call 911 or an ambulance, then give artificial respiration,
	preferably by mouth-to-mouth, if possible.
	Call a poison control center or doctor for further treatment advice.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.
	• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing
	eye.
	Call a poison control center or doctor for treatment advice.
If	Call poison control center or doctor immediately for treatment advice.
swallowed	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to do so by the poison control center or doctor.
	Do not give anything by mouth to an unconscious person.
Have the product container or label with you when calling a poison control center or doctor, or going	
for treatment. For emergency information concerning this product, call the National Pesticides	
Information Center (NPIC) at 1-800-858-7378 seven days a week,	
6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu)	

### **Storage and Disposal**

Do not contaminate water, food, or feed by storage or disposal.

**Pesticide Storage:** Do not store in areas accessible to children. Keep product dry and containers covered during storage; store below 130°F.

**Container Disposal:** Nonrefillable container. Do not reuse or refill inner plastic bag or outer steel can. **Inner Plastic Bag:** Completely empty plastic bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. **Outer Steel Can:** Offer for recycling if available or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

**Pesticide Disposal:** Wastes from the use of this product may be disposed of on site or at an approved waste disposal facility.